UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,036	09/30/2002	Paul R. Sanberg	1372.623.PRCWOUS	5509

21901 7590 03/09/2010

SMITH HOPEN, PA
180 PINE AVENUE NORTH
OLDSMAR, FL 34677

EXAMINER	
KOLKER, DANIEL E	
ART UNIT	PAPER NUMBER
1649	

NOTIFICATION DATE	DELIVERY MODE
03/09/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATENTS@SMITHHOPEN.COM
ajhopen@yahoo.com
PAIR@SMITHHOPEN.COM

Office Action Summary	Application No.	Applicant(s)	
	10/009,036	SANBERG ET AL.	
	Examiner	Art Unit	
	DANIEL KOLKER	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4,7,10,12-17,19,20 and 22-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2,4,7,10,12-17,19-20,22-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The remarks and amendments filed 4 November 2009 have been entered. Claims 1-2, 4, 7, 10, 12-17, 19-20, and 22-30 are pending and under examination.

Withdrawn Rejections

2. The following rejections set forth in the previous office action are withdrawn:

A. The rejection of claims 7, 10, 12-17 and 19 under 35 USC 103(a) as obvious over Sanberg 1996, Weiss, and Uchida is withdrawn in light of the amendments. Each of the independent claims now requires administering about 6 million cells, whereas previously the claims encompassed administering at least 6 million cells. The examiner had set forth reasons why one of ordinary skill in the art would have found it obvious to administer 38 million cells, which is not reasonably "about 6 million" cells as now claimed. Note however the new rejections under 35 USC 103(a), necessitated by applicant's amendments.

B. The rejections under 35 USC 103(a) over Dinsmore in view of Grabowski, either alone or further in view of Larazov-Spiegler, are withdrawn in light of the amendment to claim 20. The cited references do not suggest administration of about 6 million cells as claimed.

Objections and Rejections Necessitated by Amendment

Claim Objections

3. Applicant is advised that should claim 22 be found allowable, claim 23 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Claim 23 is identical to claim 22.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 4, 7, 10, 12-17, 19-20, and 22-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Independent claims 1, 7, 10, 13-15, 17, and 20 have each been amended to require administration of "about 6 million" cells to a patient. Previously the claims had been drawn to administration of "at least 6 million" (claims 1, 7, 10, 13-15, and 17) or "at least 2 million" (claim 20) cells. Applicant states (remarks filed 4 November 2009, p. 5 second paragraph) that support for the amendment from "at least" 2 or 6 million cells to "about 6 million" can be found in the original specification and figures. Applicant did not point to any particular part of the specification, or to any particular figure.

The examiner has closely reviewed the specification and figures as originally filed and cannot find disclosure of administration of "about 6 million" cells as now claimed. The specification unquestionably discloses administration of 6 million cells; see for example p. 13 lines 13-20 and p. 14 lines 1-29. The disclosure as originally filed also provides support for more than 6 million cells; see for example original claim 1, drawn to administration of "at least 2 million cells"; applicant has clearly contemplated administering cells with no upper limit on the total number of cells. However, the amendment to the independent claims has broadened the scope of the claims beyond what was originally disclosed. The disclosure as originally filed fails to provide support for methods of administering "about 6 million cells". That is, the specification, figures, and claims as originally filed do not disclose administering slightly more than 6 million cells or slightly less than 6 million cells. Therefore each of independent claims 1, 7, 10, 13-15, 17, and 20 encompasses new matter. The remaining claims are rejected as they depend from a rejected base or intermediate claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 – 2, 4, 17, 20, 22-28, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss (U.S. Patent 5,851,832) in view of Sanberg (1997. Soc. Neurosci Abstr 23(1-2):346, abstract 140.9) and Grabowski (1994. Exp Neurol. 127(1):126-136).

This rejection stands for the reasons previously made of record with respect to claims 1-2, 4, and 17 and explained in further detail below. The rejections is also extended to claims 20, 22-28, and 30 as necessitated by applicant's amendment of claim 20.

Briefly, Weiss '832 patent teaches methods of treating diseases, including stroke, by administration of the progeny of human neural stem cells. Weiss teaches that 1 – 3 ul of cells at up 50 x 10^6 cells per ml were administered (see column 62 lines 15 – 40) to rats. This corresponds to up to 150,000 cells per animal. Assuming a weight of about 0.3 kg, this is a dose of 500,000 cells per kg of body weight. Weiss explicitly teaches using burr holes to provide entry to the skull (column 62 lines 30 – 40), which is in point to claim 2. However Weiss does not teach hNT neuronal cells, does not explicitly teach "a plurality of brain area sites", as recited in claims 1 and 17 and does not explicitly teach treatment of humans who have experienced stroke at least 3 hours prior to treatment, as recited in claim 1.

Sanberg teaches that hNT cells, transplanted into the brains of rats who had experienced ischemia-inducing surgery a month earlier, are effective to ameliorate behavioral symptoms of stroke. Sanberg teaches that of the doses tested (5,000 – 40,000 cells administered to adult rats), 40,000 cells was the most effective and 5,000 and 10,000 cells were not effective; 20,000 cells per rat was effective in some but not all subjects. The reference therefore is on point to treating stroke with hNT cells; however Sanberg does not explicitly teach administering the cells to humans and does not teach administration of about 6 million cells, or a plurality of sites as recited in claims 1 and 17. Further Sanberg does not explicitly teach using a

burr to enter the brain as recited in claim 2 and does not teach administration of cells 3 months after the stroke as encompassed by claim 4.

Grabowski et al. teach another model of transplantation in which fetal cortex is grafted into the infarcted cortex of rats that having undergone middle cerebral artery occlusion 5-7 days, 3 weeks, or 8 weeks prior. The reference therefore is on point to treatment of stroke by administration of cells into the brains of affected patients. Grabowski teaches that when transplantation surgery is delayed, graft survival is significantly improved. These investigators conclude that a delay between lesion and transplantation is desirable in this stroke model. However Grabowski does not explicitly teach waiting at least 3 months as recited in claim 4, and does not teach hNT neuronal cells, does not explicitly teach "a plurality of brain area sites" as recited in claim 1.

It would have been obvious to one of ordinary skill in the art to modify the methods of Weiss, who teaches treatment of stroke by administering neural stem cells and indicates that such treatments will also be effective in humans, by substituting the hNT cells of Sanberg and by waiting at least 5-7 days, as taught by Grabowski. Additionally, it would have been obvious to one of ordinary skill in the art to use about 6 million cells, given the teachings of Sanberg. The motivation to do modify the methods of Weiss would be to effectively treat stroke in humans. It would have been reasonable to expect success as well.

Applicant continues to traverse the examiner's determination of obviousness. Applicant makes the following arguments, each of which will be addressed in turn:

1) Weiss fails to teach the efficacy of about 6 million hNT cells, and that this deficiency is not remedied by either Sanberg or Grabowski (remarks, pp. 5-6);

2) Weiss fails to teach waiting at least three hours, and this deficiency is not remedied by either Sanberg or Grabowski (remarks, p. 6 final paragraph); and

3) Weiss fails to teach waiting at least three months, and this deficiency is not remedied by either Sanberg or Grabowski (remarks, p. 7 first paragraph).

The arguments have been fully considered but they are not persuasive. With respect to 1) above, the examiner concedes that Weiss does not teach administering about 6 million hNT cells to human subjects. However, the examiner disagrees that this deficiency is not remedied by either Sanberg or Grabowski. As set forth previously, Sanberg 1997 teaches that administering 20,000 hNT cells to rats that had been subjected to a stroke was at least partly effective in treating that stroke. Specifically, Sanberg states that "[s]ome animals that received

20,000 hNT cells also displayed some significant behavioral recovery, but animals that received 0, 5000, or 10,000 hNT cells did not exhibit any significant behavioral improvement." This provides very strong guidance as to the effective doses of hNT cells in treating stroke. 20,000 cells is effective in at least some animals, whereas 5000 cells clearly is not. Assuming a rat weighs 0.3 kg and a person weighs 75 kg (165 lbs., note that the examiner took official notice of these weights previously, for example at p. 4 final paragraph of the office action mailed 6 February 2009 and these figures have not been contested by applicant), if the dose were scaled up based upon body weight, 40,000 cells administered to a 0.3 kg rat would correspond to 5,000,000 cells administered to a human. Clearly 5,000,000 cells is "about 6 million cells" as recited in independent claims 1 and 17. Thus while none of the references explicitly teaches administering "about 6 million cells" to a human patient, the reference by Sanberg clearly provides guidance to the efficacy of 5,000,000 cells in an adult human.

With respect to 2), the examiner acknowledges that Weiss does not explicitly teach waiting at least three hours between the time of stroke and the time of administration of therapeutic cells as recited in claim 1. However, this deficiency is remedied by Sanberg. In fact, Sanberg explicitly teaches that hNT cells are efficacious in treatment of stroke a month, which is clearly “at least three hours” following the occurrence of stroke. Sanberg teaches that "1 month post-ischemic surgery, animals that exhibited significant dysfunction... were transplanted with ... hNT cells". As set forth above, the reference indicates that 20,000 cells administered to rats a month after ischemia (stroke) is effective in ameliorating the effects of stroke. Thus Sanberg provides one of skill in the art with both guidance to wait more than three hours between stroke and treatment with hNT cells, as well as a reasonable expectation of success.

With respect to 3), the examiner acknowledges that Weiss does not explicitly teach waiting at least three months between the time of stroke and the time of administration of therapeutic cells as recited in claim 4. However this deficiency is cured by both Sanberg and Grabowski, taken together. Sanberg provides evidence that hNT cells are efficacious when administered one month after stroke. Grabowski provides evidence that other cells (neural grafts) are effective when administered 8 weeks after stroke (p. 127 3rd paragraph for indication that 8 weeks was the time after MCAO, or stroke; see also p. 131 first column for teaching that grafted tissue survives better when delay between MCAO and cell administration is 8 weeks as compared to one day). 8 weeks was the longest time tested by Grabowski. While none of the

references explicitly teaches waiting three months, given that Sanberg found success with a one-month delay using the same cells as recited in the present methods, and Grabowski found success with an 8-week delay, albeit with a different cell population, one of ordinary skill in the art would have had a reasonable expectation of success in selecting a 3 month period, as in claim 4. Such an increased delay would have been obvious to one of ordinary skill in the art and would have been arrived at by routine optimization. While only result-effective parameters are considered routine to optimize (MPEP § 2144.05(B)), Grabowski explicitly provides guidance that delay between MCAO (ischemic stroke) and treatment with foreign cells is one of the parameters that should be optimized.

For at least the reasons above, the rejection of claims 1-2, 4, and 17 as obvious over Weiss in view of Sanberg and Grabowski is maintained.

Claim 20 is newly included in this rejection as well. Note that the claim recites no limitations beyond those previously addressed in this rejection. The references render obvious administering to more than one brain site (which is indistinct from a plurality of brain sites as recited in claim 1), to a human who has had a stroke, about 6 million hNT cells. hNT cells are neural cells and are encompassed by claims 27-28. While the references do not explicitly teach that morbidity would be decreased over at least a year, that is not an active step recited by claim 20 but rather is an effect which will occur once the method is performed. Claims 22 and 23 are included in this rejection as administering to more than one site within the infarct area would have been obvious (see in particular Grabowski who teaches administration within infarcted areas). Claim 24 is included as sterotactic injection would have been obvious; see Weiss column 24 lines 13-20. Claims 25-26 are included as the claim recites outcomes which will happen upon performing the method which is obvious, and does not recite any additional starting materials or method steps. As described above, the references provide both a motivation to perform the methods with a 3-month delay and a reasonable expectation of success, as in claim 30.

6. Claims 1 – 2, 4, 17, 20, and 22-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss in view of Sanberg 1997 and Grabowski as applied to claims 1 – 2, 4, 17, 20, 22-28, and 30 above, and further in view of Larazov-Spiegler 1996 (FASEB J. 10:1296-1302).

The reasons why claims 1 – 2, 4, 17, 20, 22-28, and 30 would have been obvious to one of ordinary skill in the art are set forth above. However none of the cited references explicitly teaches coadministering macrophages that have been activated by exposure to peripheral nerve cells as recited in claim 29.

Larazov-Spiegler teaches that administering macrophages that have been exposed to a peripheral nerve, in particular sciatic nerve segments, is therapeutic for damaged CNS neurons. See for example abstract, as well as paragraph spanning pp. 1297 - 1298. This is on point to claim 29. However Larazov-Spiegler does not teach treating stroke in humans, as required by independent claim 20.

It would have been obvious to one of ordinary skill in the art to modify the methods rendered obvious by Weiss in view of Sanberg 1997 and Graboswki to include administration of macrophages activated by peripheral nerves, as taught by Larazov-Spiegler, thereby arriving at the invention of claim 29. Doing so would have been obvious to one of ordinary skill in the art, as each product (the porcine fetal neurons and the activated macrophages) was known to be effective for treating damaged CNS tissue, so coadministering them would have been obvious.

Applicant did not traverse the examiner's determination that performing the additional step recited in claim 29 would have been obvious in light of the disclosures by Larazov-Spiegler.

7. Claims 7, 10, 12-17, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanberg (1996. Soc. Neurosci. Abstr. 22(1-3):578, abstract 232.9) in view of Sanberg (1997. Soc. Neurosci Abstr 23(1-2):346, abstract 140.9), Weiss (U.S. Patent 5,851,832), and Uchida (1995. Exp. Neurol 132:194-208).

Sanberg 1996 teaches that transplantation of human teratocarcinoma neuronal cells (hNT) to ischemic rats produces recovery of motor function and passive avoidance behavior. The reference is therefore on point to claims 10, drawn to strokes which interfere with movement. Adult rats were subjected to ischemic embolism by middle cerebral artery occlusion were allowed to recover for one month before being tested for asymmetric motor behavior (elevated body swing task, EBST, which is a movement test) and passive avoidance behavior, a cognitive test. Sanberg 1996 teaches that one month following transplantation of hNT cells, significant recovery in both the EBST and passive avoidance tasks was observed in groups that received hNT cells as compared to controls. Control animals were reported to show no behavioral recovery. Sanberg concludes that transplantation of hNT cells into the infarcted

striatum of rats having stroke improves motor and cognitive deficits associated with such ischemia, and therefore is on point to claims 10, 12, 13, and 15. As the EBST requires sensory input, the reference is on point to claim 14 as well. Additionally, as speech is known to be one of several motor components affected by stroke, the reference is also on point to claim 7. However Sanberg does not teach administration to humans and does not explicitly teach administration of about 6 million cells as recited in claims 7, 10, 13-15, and 17 and does not explicitly teach sterile compositions.

Sanberg 1997 teaches that hNT cells, transplanted into the brains of rats who had experienced ischemia-inducing surgery a month earlier, are effective to ameliorate behavioral symptoms of stroke. Sanberg 1997 teaches that of the doses tested (5,000 – 40,000 cells administered to adult rats), 40,000 cells was the most effective and 5,000 and 10,000 cells were not effective; 20,000 cells per rat was effective in some but not all subjects. The reference therefore is on point to treating stroke with hNT cells; however Sanberg 1997 does not explicitly teach administering the cells to humans and does not teach administration of about 6 million cells and does not explicitly teach sterile compositions.

Weiss ('832 patent) teaches a method for the treatment of neurodegenerative diseases comprising administering to a mammal (such as a human) neural stem cell progeny (which may also be derived from humans) that have been induced to differentiate into neurons and/or glia (column 11, lines 13-17). The patent teaches that acute brain injuries (such as stroke) often result in the loss of neural cells, leading to inappropriate functioning of the affected brain region (column 3, lines 22-24). As disclosed by the '832 patent, treatment of neurodegenerative disease using progeny of human neural stem cells involves first having the patient undergo a CT scan to determine the coordinates of the region to receive the transplant, then using injection cannula to inject the tissue suspension to the correct coordinates (column 42, example 14). It would be an expected property of the injected cell compostion to be sterile if it was used therapeutically in humans. Note Weiss explicitly teaches collection of tissue by sterile technique (Example 14 among others) and administration of sterile saline (Example 15) as a control; thus it is reasonable that the cells administered in the same experiments are in fact in a sterile composition. Weiss teaches administration of progeny of neural stem cells to mice and rats by administering 1 – 3 ul of cells (column 62) at up to 50 x 10^6 cells per ml. This corresponds to up to 150,000 cells per animal. However Weiss does not teach administration of hNT cells as

recited in claims 7, 10, 12 – 15, 17, and 19, and does not teach administration into the cisternae as recited in claim 16.

It would have been obvious to one of ordinary skill in the art to modify the method of Sanberg 1996, who teaches administration of hNT cells to animals with cognitive, sensory, and motor damage from strokes, by following the guidance set forth in Sanberg 1997, Weiss '832 patent and Uchida. Sanberg 1997 provides guidance as to the effective dose; as set forth in the paragraph spanning pp. 5-6 of the present office action, 20,000 cells administered to a rat corresponds to 5,000,000 cells administered to a human when scaled up to the larger weight of humans. Weiss provides guidance as to treatment of human patients suffering from stroke with neural cells. Additionally, Uchida provides the artisan with guidance to select intraventricular administration, which is on point to "into the cisternae" as recited in claim 16. The artisan would have been further motivated to inject the cells cisternally, not only because Uchida teaches that implanted neuronal cells can migrate some distance from their implantation site, but also because the an intracisternal injection can be performed without drilling into the skull and is therefore less invasive and would reasonably be expected to result in fewer potential complications. Uchida also provides the motivation to select additional cell types, including fetal non-human cells and neural stem cells which are present in the embryonic neural plate used (see p. 197 second column from Uchida); it is obvious to co-administer two treatments known to be effective for the same purpose. Here, both the hNT cells from Sanberg and the neural stem cells in the composition from Uchida are both known to be suitable for transplantation into brain for therapeutic purposes. Additionally it would have been obvious to one of ordinary skill in the art to treat stroke which "interferes with speech", as this is a type of motor disorder caused by stroke. Given that Sanberg teaches therapeutically treating rats with motor disorders caused by stroke following administration of hNT cells, it would have been obvious to one of ordinary skill in the art to treat human motor deficits, including those related to speech.

In the remarks filed 4 November 1999, applicant argues that Sanberg 1996 fails to teach administration of about 6 million cells. Due to applicant's amendment to recite "about 6 million cells", the examiner has now included Sanberg 1997 in the grounds of rejection, as the 1997 reference provides guidance as to the effective dose of hNT cells that should be administered to a patient following stroke. Applicant also argues that Uchida fails to provide sufficient guidance for claim 15, drawn to a method of administering the cells to a location from which they migrate. The examiner acknowledges that the reference indicates that one or more mechanisms may

occur. However, the reference still provides guidance to perform the method of claim 15, and also provides a reasonable expectation of success.

Conclusion

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIEL KOLKER whose telephone number is (571)272-3181. The examiner can normally be reached on Mon - Fri 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Daniel E. Kolker/
Primary Examiner, Art Unit 1649
March 2, 2010